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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,390	12/17/2001	Manuel Vega	37851-912	5547
24961	7590	03/24/2004	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP 4350 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122-1246			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/022,390

**Applicant(s)**

VEGA ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1- 93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1- 93 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to an AAV, classified in class 435, subclass 235.1.

If applicant elects Group I, then they must elect one sequence for examination from claim 1 or 2, elect cap or rep from claim 3, and elect one serotype of AAV from claim 5 .

- II. Claims 6- 11, 13, 39, 88, drawn to a mutant rep protein, classified in class 530, subclass 350.

If applicant elects Group I, then they must elect one mutation from the list in claim 6 as well as choose the type of mutation (insertion, deletion, or substitution), elect cap or rep from claim 3, and elect one type of AAV rep from claim 7, elect one serotype from claim 8, and elect increase (claim 9) or decrease (claim 10).

- III. Claims 40- 42, drawn to a fusion protein, classified in class 530, subclass 350.

- IV. Claim 14, drawn to a mutant adenovirus rep protein, classified in class 530, subclass 350.

If applicant elects Group IV, then they must elect one position mutation for examination as well as the type of mutation(insertion, deletion, or substitution).

- V. Claim15, drawn to nucleic acid, classified in class 536, subclass 23.1.

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- VI. Claims 16 and 17, drawn to an rAAV and cell, classified in class 435, subclass 235.1.
- VII. Claim 18, drawn to a collection of AAV, classified in class 435, subclass 235.1.
- VIII. Claim 19, drawn to a collection of nucleic acid, classified in class 536, subclass 23.1.
- IX. Claim 20, drawn to a nucleic acid, classified in class 536, subclass 23.1.  
If Applicant elects Group IX, then Applicant must elect one sequence for examination.
- X. Claim 21, drawn to a rep protein, classified in class 530, subclass 350.  
If Applicant elects Group X, then Applicant must elect one sequence for examination.
- XI. Claim 22, drawn to a rep protein, classified in class 530, subclass 350.  
If Applicant elects Group XI, then Applicant must elect one sequence for examination.
- XII. Claims 23 and 24, drawn to a method to express rep, classified in class 435, subclass 69.1.
- XIII. Claims 25 and 32, drawn to a AAV genome, classified in class 536, subclass 23.1.

If applicant elects Group XIII, then they must elect one type of mutation(insertion, deletion, or substitution) and one mutation/sequence from claims 26- 29 for examination.

- XIV. Claims 30 and 31, drawn to a method of expressing rep, classified in class 435, subclass 69.1.
- XV. Claim 33, drawn to a method of titrating virus, classified in class 435, subclass 5.
- XVI. Claims 34- 38, drawn to a method for producing AAV, classified in class 435, subclass 235.1.
- XVII. Claims 44, and 89- 92, drawn to a mutant rAAV, classified in class 435, subclass 235.1.  
  
If applicant elects Group XVII, then they must elect one mutation from the list in claim 89 as well as choose one type of AAV rep from claim 90.
- XVIII. Claims 45 and 46, drawn to a nucleic acid and a cell, classified in class 435, subclass 235.1.
- XIX. Claims 47, 48, and 93, drawn to an AAV, classified in class 435, subclass 235.1.
- XX. Claim 49, drawn to a method to make rAAV, classified in class 435, subclass 235.1.
- XXI. Claims 50- 52, drawn to drawn to a method to make rAAV, classified in class 435, subclass 235.1.
- XXII. Claims 53- 55, drawn to a method for producing rep protein in a host cell, classified in class 435, subclass 69.1.

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XXIII. Claim 57, drawn to a method to treat or inhibit HIV or HPV, classified in class 424, subclass 187.1.

XXIV. Claims 57- 64, drawn to a nucleic acid, classified in class 536, subclass 23.1.

If applicant elects Group XXIV, then they must elect one sequence for examination, Each claim recites a different sequence and applicant must choose one for examination.

XXV. Claims 65- 86, drawn to an rAAV, classified in class 435, subclass 235.1.

If applicant elects Group XXIX, then they must elect one set of virus and cell for examination. Each set is different. For example one inventive group would be claims 65 and 73, another would be claims 68 and 76.

XXVI. Claims 81 and 82, drawn to a method for expression of intracellular expression of rep, classified in class 435, subclass 69.1.

XXVII. Claims 83 and 84, drawn to a method for expression of intracellular expression of rep, classified in class 435, subclass 69.1.

XXVIII. Claim 85- 87, drawn to a method for altering expression of a gene, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, VI, VII, XVII, XIX, XXV, (virus), II, III, IV, X, XI (protein), and V, VIII, IX, XIII, XVIII, XXIV (nucleic acid) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different structures that have different mutations and the products can be used for different methods.

Inventions XXIII, XII, XIV, XV, XXII, XXVI- XXVIII and XVI, XX, XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods that have different starting materials and different results.

Inventions II, III, IV, X, XI and XII, XIV, XV, XXII, XXVI- XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins can be used to make virus or express rep intracellularly. The nucleic acids ( I, VIII, IX, XIII, XVIII, and XXIV ) can be used to make rep protein or virus or to express protein intracellularly.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, different structures, and different methods which do not have coextensive searches, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Also, if applicant elects a group that depends from a claim that requires an election of sequence, serotype, or mutation, that must be elected as well.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product



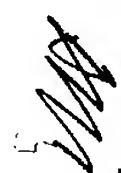
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claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
March 22, 2004



JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600